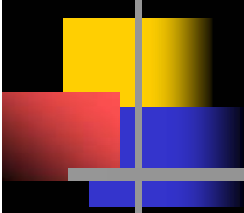


# Can a second rapid HIV test discriminate false positives as effectively as a Western Blot? The NJ Experience

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Evan M. Cadoff, MD  
Robert Wood Johnson Medical School  
New Brunswick, NJ

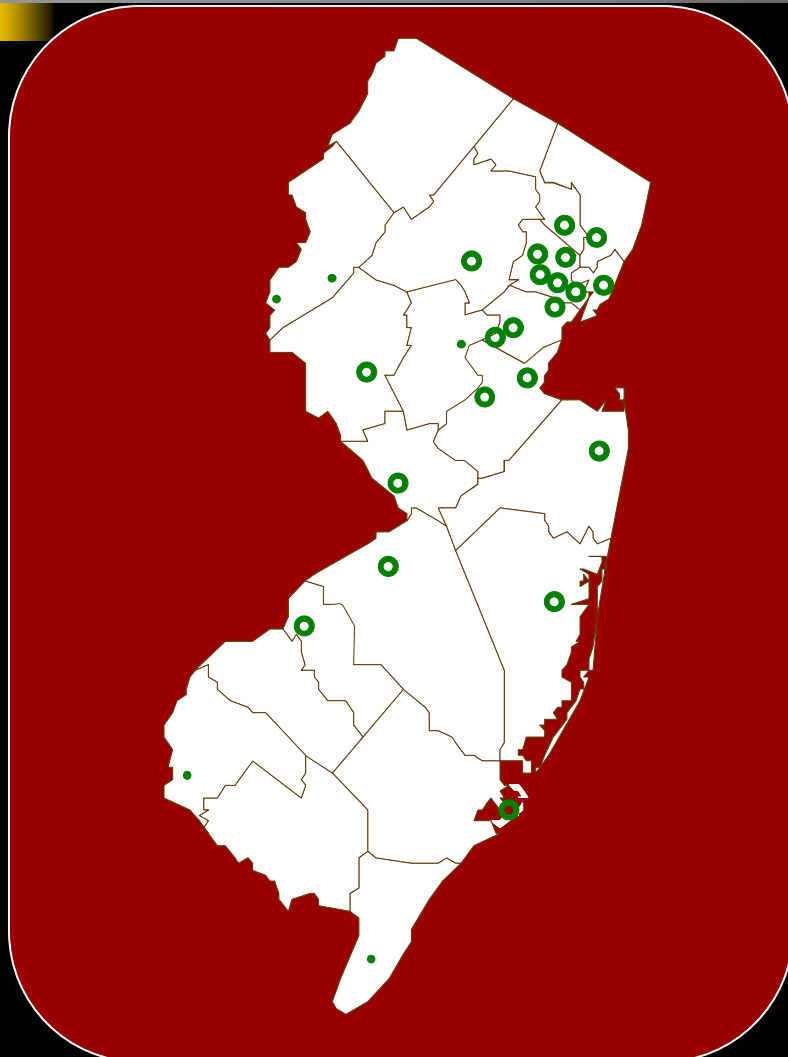


# Can a second rapid HIV test confirm preliminary positives as effectively as a Western Blot? The NJ Experience

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Evan M. Cadoff, MD  
Robert Wood Johnson Medical School  
New Brunswick, NJ

# New Jersey CTS sites



- 23 primary sites

Pre-rapid testing:

- Specimens sent to state lab in Trenton
- 2.3-2.6% seroprevalence
- 65% receive post-test counseling
- 35% do not return for results

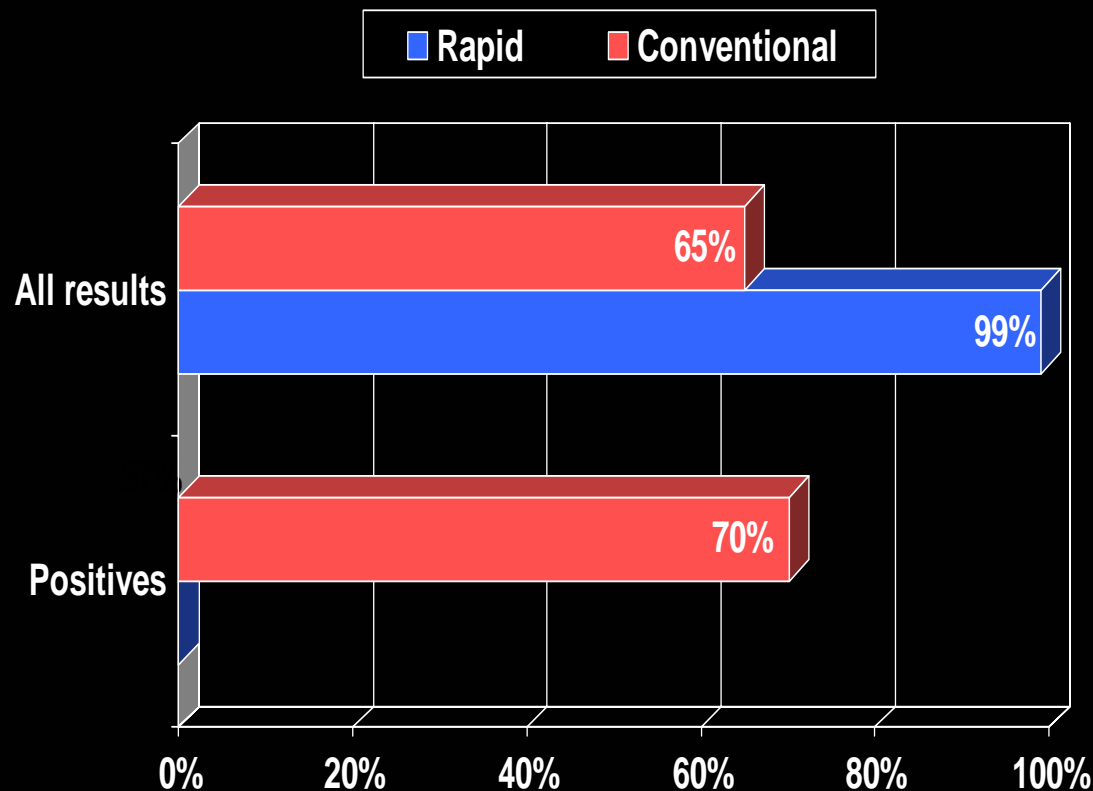
# New Jersey rapid testing

OraQuick started Nov 1, 2003:

- 23 primary sites
- 32 satellite licenses
- Western Blot confirmation at state lab in Trenton
- Over 70 CTS sites, including:
  - Hospitals/EDs
  - FQHCs
  - CBOs
  - Health departments
  - Six mobile vans
  - Community events



# Clients receiving post-test counseling

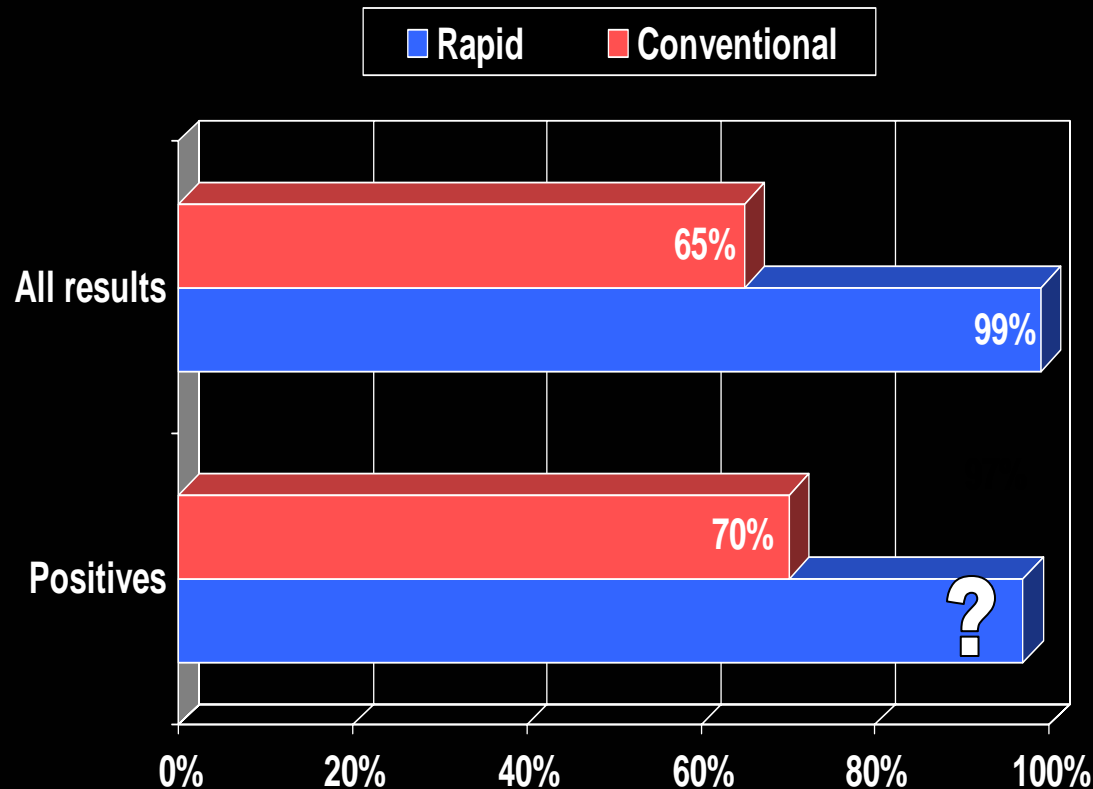


Marked improvement with introduction of rapid testing

Preliminary positives:

- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling

# Clients receiving post-test counseling



Marked improvement with introduction of rapid testing

Preliminary positives:

- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling

Can we extend our success to preliminary positives?



# Questions for rapid confirmation

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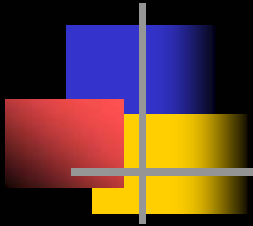
- Will a finger stick be more acceptable for confirmation
- Can rapid immunoassays perform as well as the 'gold standard' Western Blot?



## BBI Seroconversion Panel Results:

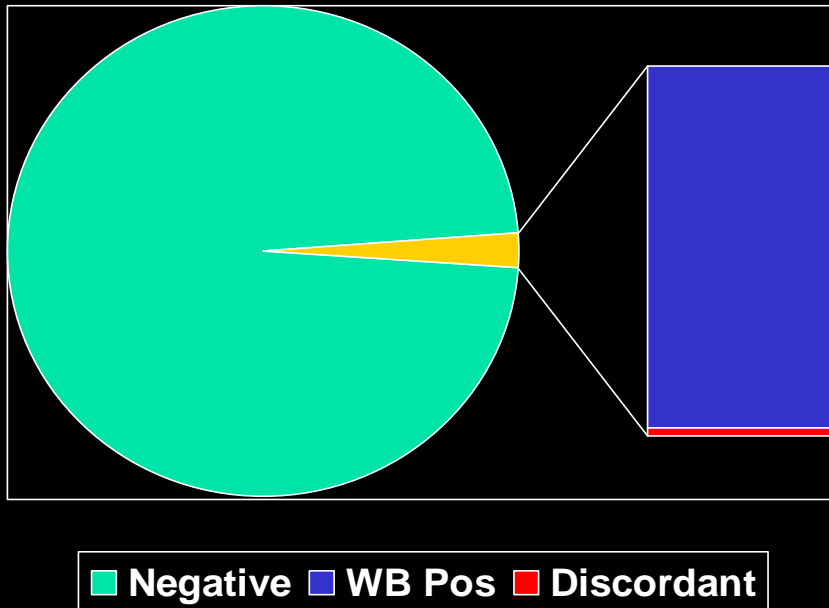
Member #	Days since first bleed	EIA	Western blot	Viral load	Rapid test
PRB959-01	0	0.1	No bands	$2 \times 10^5$	N
PRB959-02	7	0.1	No bands	$>8 \times 10^5$	N
PRB959-03	9	0.2	No bands	$>8 \times 10^5$	N
PRB959-04	14	1.8	p24, gp160	$8 \times 10^5$	P
PRB959-05	19	7.3	p24, gp160	$5 \times 10^5$	P
PRB959-06	21	7.6	p24, gp160	$3 \times 10^5$	P
PRB959-07	26	7.8	p24, gp160	$>8 \times 10^5$	P



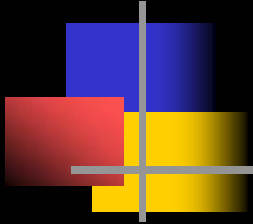


# Rapid confirmation trial

July 1, 2004 through April 19, 2005



- 15,923 OraQuick tests statewide
- 363 preliminary positive samples to state lab for confirmatory testing
  - 355 Western Blot positive
  - 8 Western Blot negative



# Rapid confirmation trial

---

- All 8 Western Blot negative clients:
  - Part of CDC Post-marketing surveillance study
  - Negative on follow-up at least 4 weeks later, both antibody and nucleic acid testing
  - 4 of 7 tested reacted with non-viral components of OraQuick device

**All 8 were false positive OraQuick tests**

# Rapid confirmation trial

All samples run by:

- Trinity Uni-Gold
- BioRad Multispot
- OraSure OraQuick
- MedMira Reveal



## Confirmatory test results

	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
<b>OraSure OraQuick</b>	<b>8 positive</b>	<b>355 positive</b>
Trinity Uni-Gold		
BioRad Multispot		
MedMira Reveal		
Followup of > 1 month	8 negative Western Blot 8 negative viral load	

## Confirmatory test results

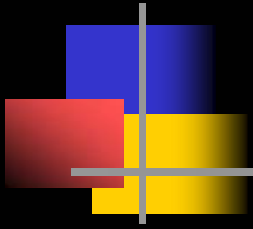
	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
OraSure OraQuick	8 positive	355 positive
<b>Trinity Uni-Gold</b>	<b>8 negative</b>	<b>355 positive</b>
BioRad Multispot		
MedMira Reveal		
Followup of > 1 month	8 negative Western Blot 8 negative viral load	

## Confirmatory test results

	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
OraSure OraQuick	8 positive	355 positive
Trinity Uni-Gold	8 negative	355 positive
<b>BioRad Multispot</b>	<b>7 negative</b> <b>1 positive</b>	<b>354 positive</b> <b>1 QNS</b>
MedMira Reveal		
Followup of > 1 month	8 negative Western Blot 8 negative viral load	

## Confirmatory test results

	8 Western Blot negative (False Positive OraQuick)	355 Western Blot positive (True Positive OraQuick)
OraSure OraQuick	8 positive	355 positive
Trinity Uni-Gold	8 negative	355 positive
BioRad Multispot	7 negative 1 positive	354 positive 1 QNS
<b>MedMira Reveal</b>	<b>8 negative</b>	<b>340 positive</b> <b>15 sample interference</b>
Followup of > 1 month	8 negative Western Blot 8 negative viral load	

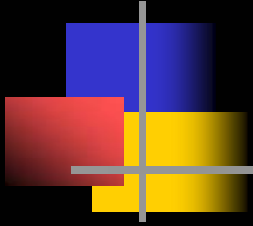


# Rapid confirmation trial

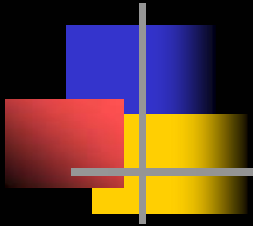
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- **Repeat OraQuick** (CLIA waived for whole blood or oral fluid)
  - All samples reproduced
  - Not approved for serum testing, or stored samples
- **UniGold** (CLIA waived for whole blood, CLIA moderate for serum)
  - All samples matched Western Blot
  - Study used serum, clinics would perform whole blood testing
- **Multispot** (CLIA moderate for serum/plasma)
  - 1 false positive
- **Reveal** (CLIA moderate for serum/plasma)
  - No false positives, or false negatives
  - Several unreadable samples





A second rapid HIV test  
can confirm a positive Oraquick  
result  
as reliably as a Western Blot.



# Western Blot Confirmation

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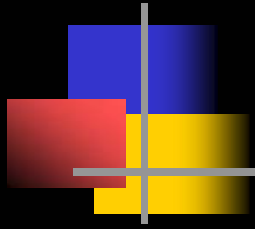
- 7.1% of positives could not be confirmed because specimens were not collected
- 25.8% did not return for results of confirmatory Western Blot
- 70.1% of confirmed positives got their confirmed result
- Western Blot confirmation has an effective sensitivity as low as 70.1%



## Using OraQuick with Uni-Gold confirmation:

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- Matched OraQuick with Western Blot confirmation in 100% of 15,923 clients studied
- Finger stick confirmation may be more acceptable than venipuncture, reducing the refusal rate
- Rapid confirmation may virtually eliminate the non-returners
- Effective sensitivity may approach 99-100%
- Counseling, contact elicitation and referral for treatment can be done immediately

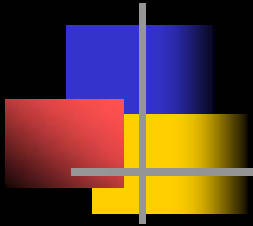


## Next steps

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Prospective evaluation of algorithm of OraQuick with Uni-Gold confirmation:

- Real world performance of a rapid test as confirmation
- Effect on post-test counseling rate
- Reduction in time delay in delivering confirmed result to clients using different confirmatory test algorithms
- Expansion to Notification Assistance Program



# Thanks to:

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- Nisha Intwala
- Vivian Shih
- Melonie Rogers

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- Rose Marie Martin
- Maureen Wolski
- Lorhetta Nichol
- Phil Bruccoleri\*
- Aye Maung Maung

## NJDHSS/PHEL

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- Kanjana Garcia

